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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-385]

**Schedules of Controlled Substances: Temporary Placement of Four Synthetic
Cannabinoids into Schedule I**

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of Intent.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of intent to temporarily schedule four synthetic cannabinoids into Schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). The substances are: quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC); quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to Schedule I substances under the CSA on the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of these synthetic cannabinoids.

DATES: [insert date of publication in the Federal Register]..

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Acting Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone (202) 598-6812.

SUPPLEMENTARY INFORMATION: Any final order will be published in the Federal Register and may not be effective prior to [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Background

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of the DEA, who in turn has delegated her authority to the Deputy Administrator of the DEA. 28 CFR 0.100, 0.104, Appendix to Subpart R of Part 0, Sec. 12.

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.¹ As PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are not currently listed in any schedule under the CSA, the DEA believes that the conditions of 21 U.S.C. 811(h)(1) have been satisfied. Any comments submitted by the Assistant Secretary in response to the notice transmitted to the Assistant Secretary on November 7, 2013, shall be taken into consideration before a final order is published. 21 U.S.C. 811(h)(4).

To make a finding that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in Schedule I. 21 U.S.C. 811(h)(1). Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA indicate that these

¹ Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this Notice of Intent, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

four synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

Synthetic Cannabinoids

Synthetic cannabinoids are a large family of compounds that are functionally (biologically) similar to delta9-tetrahydrocannabinol (THC), the main active ingredient in marijuana. Synthetic cannabinoids, however, are not organic but are chemicals created in a laboratory. Two of the synthetic cannabinoids currently controlled (CP-47,497 and cannabicyclohexanol) were first synthesized in the early 1980's for research purposes in the investigation of the cannabinoid system. JWH-018, JWH-073, and JWH-200 (temporarily scheduled on March 1, 2011 at 76 FR 11075 and permanently scheduled on July 9, 2012, by Section 1152 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112-144) were synthesized in the mid-1990s and studied to further advance the understanding of drug-receptor interactions regarding the cannabinoid system. Synthesized as research tools, no other known legitimate uses have been identified for these five synthetic cannabinoids.

According to forensic laboratory reports, the initial appearance of synthetic cannabinoids in herbal incense products in the United States occurred in November 2008 when U.S. Customs and Border Protection (CBP) first encountered products using brand names such as "Spice." Prior to appearing on the U.S. market, synthetic cannabinoids were marketed in herbal incense products in several European countries. After experiencing numerous health-related incidents, some European countries banned these products/chemicals. According to CBP, a number of the synthetic cannabinoids appeared to originate from foreign sources.

Detailed chemical analyses by DEA and other agencies have found synthetic cannabinoids applied on plant material in herbal incense products marketed to the general public.

Product analyses have found variations in both the type of synthetic cannabinoid and the amount of the substance found on the plant material.

The vast majority of cannabinoids are manufactured in Asia by individuals who are not bound by any manufacturing requirements or quality control standards. The bulk products are smuggled into the United States typically as misbranded imports. These chemicals are generally found in powder form or are dissolved in solvents, such as acetone, before being applied to the plant material comprising the “herbal incense” products. After local distributors apply the drug to the leafy material, they package it for retail distribution, ignoring any control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of drug in each package. According to Internet discussion boards and law enforcement encounters, spraying or mixing the synthetic cannabinoids on plant material provides a vehicle for the most common route of administration- smoking (using a pipe, a water pipe, or rolling the drug-spiked plant material in cigarette papers). They are sold under hundreds of different brand names, including “Spice,” “K2,” “Blaze,” “Red X Dawn,” “Paradise,” “Demon,” “Black Magic,” “Spike,” “Mr. Nice Guy,” “Ninja,” “Zohai,” “Dream,” “Genie,” “Sence,” “Smoke,” “Skunk,” “Serenity,” “Yucatan,” “Fire,” and “Crazy Clown.”

Law enforcement personnel have encountered dosage form and packaging operations in residential neighborhoods, garages, and warehouses. Throughout this process, there is no concern for preventing contamination of the product, consistent dosage, or the adverse health consequences that may occur from ingesting the drug. As proposed in the scientific literature, the risk of adverse health effects is further increased by the fact that similarly labeled products vary in the composition and concentration of synthetic cannabinoids applied on the plant material.

There is an incorrect assumption that these products are safe. Numerous states, local jurisdictions, and the international community have controlled many synthetic cannabinoids. These substances have no accepted medical use in the United States and have been reported to produce adverse health effects in those who abuse them.

PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA are synthetic cannabinoids that have pharmacological effects similar to the Schedule I hallucinogen delta-9-tetrahydrocannabinol (THC). PB-22 and 5F-PB-22 were not reported in the scientific literature prior to their appearance on the illicit drug market. First appearing in a 2009 patent filed by the pharmaceutical manufacturer Pfizer, AB-FUBINACA was most recently reported in the scientific literature as a component of so-called “herbal products” purchased via the Internet in July 2012. ADB-PINACA was first encountered by law enforcement following reports of serious adverse events in Georgia and Colorado in August and September 2013, respectively.

From January through November 2013, according to the System to Retrieve Information from Drug Evidence (STRIDE)² there were 189 reports involving PB-22, 155 reports involving 5F-PB-22, and 42 reports involving AB-FUBINACA (Queried on December 18, 2013). From January through November 2013, the National Forensic Laboratory Information System (NFLIS)³ registered 1,092 reports containing PB-22 in 29 states, 1,058 reports containing 5F-PB-22 in 25 states, 458 reports containing AB-FUBINACA in 17 states and 9 reports containing ADB-PINACA in one state (Queried on December 18, 2013). No reports in NFLIS or STRIDE were identified for PB-22 or 5F-PB-22 prior to February 2013. No reports in NFLIS or STRIDE

² STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and local law enforcement agencies.

³ NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories across the country.

were identified for AB-FUBINACA prior to June 2013 or for ADB-PINACA prior to August 2013.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids have been developed over the last 30 years as tools for investigating the cannabinoid system. Synthetic cannabinoids intended for illicit use were first reported in the United States in a November 2008 encounter, where a shipment of “Spice” was seized and analyzed by CBP in Dayton, Ohio. Additionally around the same time, in December 2008, JWH-018 and cannabicyclohexanol (CP-47,497 C8 homologue) were identified by German forensic laboratories. Since the initial identification of JWH-018, many additional synthetic cannabinoids have been found applied on plant material and encountered as designer drug products. The majority of the substances encountered on the illicit market have not been tested beyond preliminary pre-clinical laboratory screens before clandestine operators apply them on plant material.

JWH-018 was the first synthetic cannabinoid to be identified as a product adulterant in Germany in 2008. This substance was initially synthesized as a research tool to investigate the cannabinoid system. Since then, numerous other synthetic cannabinoids have been identified as product adulterants and law enforcement has seized bulk amounts of these substances. The first synthetic cannabinoids identified as being abused included JWH-018, JWH-200, JWH-073, CP-47,497 and CP-47,497 C8 homologue, followed shortly thereafter by new generations of synthetic cannabinoids that included AM2201 and others, and eventually UR-144, XLR11 and AKB48. JWH-018, JWH-073, JWH-200, CP-47,497, and CP-47,497 C8 were temporarily scheduled on March 1, 2011 (76 FR 11075), and later permanently placed in Schedule I by Section 1152 of FDASIA on July 9, 2012. Section

1152 of FDASIA amended the CSA by placing cannabimimetic agents and 26 specific substances (including 15 synthetic cannabinoids, 2 synthetic cathinones, and 9 synthetic phenethylamines of the 2C-series) in Schedule I. UR-144, XLR11 and AKB-48 were temporarily scheduled on May 16, 2013 (78 FR 28735). The most recent synthetic cannabinoids emerging as drugs of abuse include PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. These four synthetic cannabinoids, along with UR-144, XLR11 and AKB-48, were not included among the 15 specific named synthetic cannabinoids, and do not fall under the definition of cannabimimetic agents, under FDASIA.

Synthetic cannabinoid products are marketed directly to adolescents and youth who appear to be the primary abusers of synthetic cannabinoids and synthetic cannabinoid-containing products. This is supported by law enforcement encounters and reports from emergency rooms; however, all age groups have been reported by media as abusing these substances and related products.

According to recent testimony given by the Deputy Director of the Office of National Drug Control Policy (ONDCP) to the United States Senate Caucus on International Narcotics Control (September 25, 2013), current drug testing misses significant populations of synthetic cannabinoid users. This testimony describes a study showing that in a sample of men 30 years old or younger within the District of Columbia parole and probation system, 39 percent of those who cleanly passed a traditional drug screen tested positive for synthetic cannabinoids. The study continued that between one-quarter and one-third of young men who were tested in the Washington, D.C. criminal justice system had positive test results for synthetic cannabinoids, regardless of whether they had failed or passed a traditional drug screen.

Factor 5. Scope, Duration and Significance of Abuse

Recently, increased exposure incidents have been documented by poison control centers in the United States as the abuse of synthetic cannabinoids has been associated with both acute and long-term public health and safety concerns. From January through November 2013, according to STRIDE there were 189 reports involving PB-22; 155 reports involving 5F-PB-22; and 42 reports involving AB-FUBINACA (Queried on December 18, 2013). From January through November 2013, NFLIS registered 1,092 reports containing PB-22 in 29 states (Arkansas, Arizona, Colorado, Connecticut, Florida, Georgia, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Missouri, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Virginia, Wisconsin and Wyoming); 1,058 reports containing 5F-PB-22 in 25 states (Arkansas, Arizona, Colorado, Florida, Georgia, Iowa, Indiana, Kansas, Louisiana, Minnesota, Missouri, North Dakota, New Jersey, New Mexico, Nevada, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin and Wyoming); 458 reports containing AB-FUBINACA in 17 states (Arizona, Colorado, Florida, Georgia, Iowa, Indiana, Kansas, Louisiana, Minnesota, Missouri, North Dakota, New Jersey, Nevada, Ohio, Oklahoma, Pennsylvania and Texas); and 9 reports containing ADB-PINACA in one state (Colorado) (Queried on December 18, 2013). No reports in NFLIS or STRIDE were identified for PB-22 or 5F-PB-22 prior to February 2013. No reports in NFLIS or STRIDE were identified for AB-FUBINACA prior to June 2013 or for ADB-PINACA prior to August 2013.

ADB-PINACA was first encountered in the United States following reports of serious adverse events in Georgia on August 23, 2013. Reports of ADB-PINACA were not found in the scientific literature prior to its emergence on the designer drug market. The Georgia Bureau of

Investigation (GBI) reported on September 12, 2013 that ADB-PINACA was detected in “herbal incense” products sold under the brand name “Crazy Clown.” It was later confirmed by the Centers for Disease Control and Prevention (CDC) as the substance responsible for severe adverse events in at least 22 persons who consumed the product. In addition, on August 30, 2013, the Colorado Department of Public Health and Environment (CDPHE) was notified by several hospitals of an increase in the number of patients visiting their emergency departments (EDs) with altered mental status after using synthetic marijuana. On September 8, 2013, CDPHE, with the assistance of CDC, began an epidemiologic investigation whereby 221 cases of severe illness due to ingestion of a synthetic cannabinoid were identified. Those that presented at emergency rooms in the Denver, Colorado area around September 1, 2013, had symptoms similar to those found in the August 2013 Georgia incident. Laboratory analysis of samples from the Colorado incident confirmed that the substance abused in the “herbal incense” products was ADB-PINACA.

The American Association of Poison Control Centers (AAPCC) reported receiving over 2,436 calls from January to November 2013, regarding exposures to products purportedly containing synthetic cannabinoids, although the data provided does not generally include biological sample testing that would confirm to which cannabinoids the user was exposed. A majority of these exposure incidents resulted in individuals seeking medical attention at health care facilities.

Factor 6. What, if Any, Risk There is to the Public Health

The earliest reported encounter of PB-22 was by Finnish Customs (Tulli) in Helsinki who intercepted a consignment of 54 kilograms en route from China to Russia on October 27, 2012. From January through November 2013, CBP shared information related to synthetic cannabinoid

shipments encountered at United States Ports of Entry and intended for destinations within the United States: PB-22 – 25 encounters involving 69.6 kg; 5F-PB-22 – 23 encounters involving 32.9 kg; and AB-FUBINACA – 9 encounters involving 16.1 kg. The DEA has reported multiple encounters of large quantities of PB-22, 5F-PB-22 and/or AB-FUBINACA that have been confirmed by forensic laboratories (STRIDE).

In late August 2013, local law enforcement in Brunswick, Georgia reported that 22 persons ranging in age from 16 to 57 presented to emergency departments with severe adverse reactions after consuming a synthetic product called “Crazy Clown.” Adverse effects included the inability to stand, foaming at the mouth, violence towards police and paramedics and memory lapse. The substance responsible for these effects was later identified by the GBI as ADB-PINACA. In early September 2013, 221 patients presented to emergency departments in Colorado after having adverse reactions to a synthetic product labeled as “Black Mamba.” Adverse effects included having no gag reflex, inability to breathe on their own, hallucinations and psychotic episodes as described by nurses and attending physicians. The substance in the product consumed was identified as ADB-PINACA. In addition to the incidents in Georgia and Colorado, ADB-PINACA was also identified in exhibits of plant material labeled “10X” and “20X” submitted to a laboratory in Illinois on October 7, 2013.

Health warnings have been issued by numerous state public health departments and poison control centers describing adverse health effects associated with smoking (inhaling) synthetic cannabinoid products including, agitation, vomiting, tachycardia, elevated blood pressure, seizures, hallucinations, and non-responsiveness.

Medical examiner and postmortem toxicology reports demonstrate the involvement of 5F-PB-22 in the death of at least five individuals. These reports demonstrated that 5F-PB-22

was qualitatively identified in the blood and/or urine of all five of the deceased individuals. In addition, 5F-PB-22 intoxication was the sole cause of death in one case, while a second case stated that the cause of death was a fatal cardiac arrhythmia and/or fatal seizure in association with the use of 5F-PB-22.

Since abusers obtain these drugs through unknown sources, the identity, purity, and quantity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. There are no recognized therapeutic uses of these substances in the United States.

Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety

Based on the above summarized data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these synthetic cannabinoids in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA indicate that these four synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator, through a letter dated November 7, 2013, notified the Assistant Secretary of the DEA's intention to temporarily place these four synthetic cannabinoids in Schedule I.

Conclusion

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule four synthetic cannabinoids, quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC); quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), in Schedule I of the CSA, and finds that placement of these synthetic cannabinoids into Schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these synthetic cannabinoids into Schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication in the Federal Register, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Deputy Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of a Schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done “on the record after opportunity for a hearing” conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of

section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Deputy Administrator will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

Further, the DEA believes that this temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Under the authority vested in the Attorney General by section 201(h) of the CSA, 21 U.S.C. 811(h), and delegated to the Deputy Administrator of the DEA by Department of Justice regulations (28 CFR 0.100, Appendix to Subpart R of Part 0), the Deputy Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Section 1308.11 is amended by adding paragraphs (h)(15) through (18) to read as follows:

§ 1308.11 Schedule I

* * * *

(h) * * *

(15) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers – 7222 (Other names: PB-22; QUPIC)

(16) quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers – 7225 (Other names: 5-fluoro-PB-22; 5F-PB-22)

- (17) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers
– 7012 (Other names: AB-FUBINACA)
- (18) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers
– 7035 (Other names: ADB-PINACA)

Dated: January 6, 2014

Thomas M. Harrigan,
Deputy Administrator.

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